

Application No. 10/536,533
Paper Dated: September 4, 2008
In Reply to USPTO Correspondence of June 4, 2008
Attorney Docket No. 4544-051675

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1-22 (canceled).

Claim 23 (Currently Amended): A process for the preparation of an agglutination reagent for rapid and early detection of typhoid comprising:

- (a) preparing an antibody specific to *Salmonella* *Salmonella*-typhi;
- (b) preparing a latex particles-particle suspension; and
- (c) coating of the said a latex particles with the said antibody;

wherein the said process of preparing antibody specific to *Salmonella* *Salmonella*-typhi comprises is prepared according to a method comprising cloning a Flagellin gene sequence specific to *Salmonella* *Salmonella*-typhi, expressing the said Flagellin gene sequence by recombinant DNA technology thereby expressing a recombinant protein, followed by purifying said recombinant protein by affinity chromatography thereby forming a purified recombinant protein, raising the a hyper immune sera against said purified recombinant protein in animals like rabbitan animal, separating the an antibody (immunoglobulin) fraction of from said hyper immune sera by precipitating in an ammonium sulphate, suspending in a 50 mM phosphate buffer of pH 7.2, and dialyzing;

wherein the said process of preparing latex particle suspension comprises is prepared according to a method comprising:

- (i) mixing 1% carboxylated latex particles of size 0.88 to 0.90 µm and a 40 mM 2-N Morphilinoethane morpholinoethane sulphonic acid (MES) buffer of pH 5.5 to 6.0 in a ratio of 1:1 on a vortex mixer for about 60 seconds, centrifuging at 10,000 rpm for 10-12 minutes at about 4°C, followed by washing twice with a 20 mM MES buffer of pH 5.5 at 10,000 rpm for 10-12 minutes at about 4°C, sonicating by a tip sonicator at about 5 watts for 60-120 seconds, thereby forming a sonicated latex particle;

(ii) adding drop wise a freshly prepared solution of a 0.1 M 1-ethyl-3 (3-dimethyl-amino propyl)carbodiimide carbodiimide hydrochloride (EDC) in a 20 mM MES buffer of pH 5.5 to the-said sonicated latex particles obtained from step (i) above in a ratio of 1:1 while vortexing ~~the suspension slowly thereby forming a suspension~~, rotating the suspension slowly end-over-end for about 3 hours at a temperature of 20-25°C, washing thrice with a 20 mM MES buffer (pH 5.5) followed by sonicating ~~the washed said suspension of latex particles by a tip sonicator for 60-120 seconds at about 5 watts;~~

~~wherein the said process of coating of the said latex particles particle is done coated by adding 0.6-1.0 mg preferably 0.8 mg per ml of the said antibody (immunoglobulins) fraction to the said latex particle suspension thereby forming an antibody-particle mixture, rotating the said antibody-particle mixture suspension end-over-end for 18-20 hours at a temperature of about 20-25°C thereby forming a solution comprising an antibody coated latex particle, stopping the coating reaction by 1M glycine (pH 11.0) taken in quantity of 0.06 ml per ml of said solution of antibody coated latex particles followed by centrifugation at 10,000 rpm for 10-12 minutes at a temperature of about 4°C, washing thrice with a washing buffer comprised of 50 mM glycine, pH 8.5; 0.03% triton X 100 surfactant and 0.05% sodium azide, suspending in a storage buffer to a final concentration of 1%, sonicating for about 60 seconds at about 5 watts and storing at 4°C.~~

Claim 24 (Currently Amended): An agglutination reagent for rapid and early detection of typhoid, comprising of 1% carboxylated latex particles coated with antibody specific to Salmonella Salmonella typhi, suspended in storage buffer.

Claim 25 (Previously Presented): The agglutination reagent as claimed in claim 24, wherein the size of the said latex particles is 0.88 to 0.90 µm.

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Claim 26 (Currently Amended): The agglutination reagent as claimed in claim 24, wherein the said storage buffer is comprised of 50 mM glycine pH 8.5, 1.0% bovine serum albumin, 0.03% ~~triton X-100 surfactant~~, 0.1% sodium azide and 0.01% ~~thiomersal thimerosal~~.

Claim 27 (Currently Amended): The agglutination reagent for rapid and early detection of typhoid as claimed in claim 24, wherein the said antibody is the immunoglobulin fraction[[,]] of the hyper immune sera raised in ~~rabbit~~ said animals against the recombinant protein expressed by cloning of Flagellin gene sequence specific to Salmonella Salmonella-typhi by recombinant DNA technology, suspended in 50 mM phosphate buffer.

Claim 28 (Withdrawn): A kit for rapid and early detection of typhoid comprising 1% agglutination reagent as claimed in claim 24 suspended in storage buffer, glass slides, droppers, wooden sticks and positive and negative controls.

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REMARKS

According to the Office Action of June 4, 2008, claims 23-27 have been examined and have been objected to and stand rejected. Claim 28 has been withdrawn by the Examiner as directed to non-elected subject matter. Applicants expressly reserve the right to file a divisional application directed to the non-elected subject matter.

Applicants have amended the specification, and claims 23, 24, 26 and 27. In view of these amendments and the remarks below, Applicants respectfully request reconsideration and withdrawal of the asserted objections and rejections.

Objection to the Specification

On page 2, the Office Action asserts an objection against the specification, and suggests that “triton X-100” be amended to “TRITON X-100™”. Applicants have adopted this suggestion. Accordingly, withdrawal of this objection is respectfully requested.

Objection asserted against the Claims

Claims 23 and 26 have been objected to for containing typographical errors. Applicants have adopted the Examiner’s suggested amendments. Accordingly, withdrawal of these objections is respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 23-27 have been rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. Specifically, the claims have been rejected for their recitation of (1) “like rabbit”, and (2) “triton X-100”. Applicants have deleted the recitation of “like rabbit” from the claims, and have replaced “triton X-100” with “surfactant”. Accordingly, withdrawal of these rejections is respectfully requested.